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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,374

01/03/2007

Petra Tafelmeyer

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SHOEMAKER AND MATTARE, LTD  
10 POST OFFICE ROAD - SUITE 100  
SILVER SPRING, MD 20910

EXAMINER

WESSENDORF, TERESA D

ART UNIT

PAPER NUMBER

1639

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/575,374	<b>Applicant(s)</b> TAFELMEYER ET AL.	
	<b>Examiner</b> TERESA WESSENDORF	<b>Art Unit</b> 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

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**DETAILED ACTION**

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10, drawn to a method for the identification of suitable fragmentation sites in a reporter protein.

Group II, claim(s) 11-14, drawn to a recombinant DNA sequence for use in securing expression in a prokaryotic or eukaryotic host cell of a polypeptide product.

Group III, claim(s) 15-17, drawn to a first subdomain of a reporter protein and/or a complementary second subdomain of a reporter protein.

Group IV, claim(s) 18-22, drawn to a fusion protein.

Group V, claim(s) 23-24, drawn to a kit.

Group VI, claim(s) 25-28, drawn to a method for detecting an interaction between a first test peptide or protein or a fragment thereof, and a second test peptide or protein or a fragment thereof.

Group VII, claim(s) 29, drawn to a method for detecting the interruption of an interaction between a first test peptide or protein or a fragment thereof, and a second test peptide or protein or a fragment thereof (e.g., using a modulator).

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Group VIII, claim(s) 30, drawn to a process for the identification of fragmentation sites in a reporter protein for use in a two-hybrid system, comprising a step of random circular permutation of a gene and/or the expressed polypeptide derived thereof.

Group IX, claim(s) 31, drawn to a process for the generation of a recombinant DNA molecule.

The inventions listed as Groups I and VI-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: each of the process lacks a corresponding special technical features as each of the process recites distinct process steps to perform each of the corresponding method. For example, group I process steps require the creation of library to screen and identify the fragmentation sites in a reporter protein like fluorescent protein. This step does not correspond to the method of group II which determines the interaction between two proteins, thus does not require a screening step. Group VII method requires the presence of e.g., a modulator or test agent to determine the interruption of interaction between the two proteins. Thus, the process steps of each of these e.g., groups lack the same or corresponding special technical features of one process of one group from the other groups.

The inventions listed as Groups II-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: each of the compounds lack the same or corresponding special technical features. For example, the compound of group II comprises a conjugate or complex of a first and second subdomain of a reporter protein, which combination is not require or present in the individual reporter protein of group III. Hence, each of these two groups of compounds differs in structure and mode of action or function. Group IV lack the corresponding features of group II and III in that the fusion protein contains structurally different compounds fuse to the reporter protein e.g., label or tag.

Each of groups II-IV lacks the corresponding technical features of group V which requires an instruction for the kit to work.

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The inventions listed as Groups (II-V) and Groups (I and VI-IX) do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: each of groups II-V drawn to compounds lack the same or corresponding special technical features of the method steps of groups I and VI-IX, as discussed above.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

**For Group I:** (Please note that for a proper species election, applicants are to elect one species from 1, one from 2 and one from 3 and etc. as given below).

1. Reporter protein as recited in claim 1.
2. Host cell as recited in claim 3.
3. Linker sequence as recited in claim 8.
4. Tag as recited in claim 8.
5. Transcription terminating sequence as recited in claim 9.
6. Transcription promoting sequence as recited in claim 9.
7. Marker sequence as recited in claim 9.

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**For Group II:** (Please note that for a proper species election, applicants are to elect one species from 1, one from 2 and one from 3, as given below).

1. Host cell as recited in claim 11.

2. Reporter protein as recited in claim 11. Please note that an election from the reporter sequence from the proteins excluded in claim 11 is not a proper species election.

3. DNA sequence selected from a)-c). If a) is elected applicants are to elect a single DNA sequence as recited in claim 13(a).

**For Group III and Group V:**

1. First and second subdomains of reporter proteins as recited in claim 15.

**For Group IV:** (Please see note above).

1. 1. Reporter protein as recited in claim 18.

2. Peptide or Protein fuse to said reporter protein as recited in claim 18.

3. Yeast cell line as recited in claim 22.

**For Group VI and Group VII:**

1. First and second test peptides as recited in claim 25.

2. First and second subdomains of reporter protein as recited in claim 25.

3. Host cell as recited in claim 25.

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**For Group VIII and IX:**

1. Reporter protein as recited in e.g., claim 30.
2. Host cell as recited in e.g., claim 31.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Please see above.

The following claim(s) are generic: 1, 3, 11, 13, 15, 18, 22, 23, 25 and 29-31.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special

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technical features for the following reasons: each of the species recited in each of the subgroups for the different groups lack a corresponding special technical features as each differs in structure e.g., reporter sequence such as fluorescent protein from enzyme protein. The mode of action of the prokaryotic from the eukaryotic cells is different e.g., in posttranslation.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of



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an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims.

**Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA WESSENDORF whose telephone number is (571)272-0812. The examiner can normally be reached on flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/TERESA WESSENDORF/

Primary Examiner, Art Unit 1639